510(k) Summary
Codman® HAKIM® Precision and Programmable Valve System

Date Prepared: July 16, 2012

AUG 3 2012

Company Name: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Kathy Strange
Regulatory Affairs Specialist
Telephone Number: (508) 828-3257
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Device Proprietary Name: Codman® HAKIM Precision and Programmable Valve System
Device Common Name: Hydrocephalus Shunt System

Classification Name: Central Nervous System Fluid Shunt and Components

Device Classification: Class II (21 CFR§ 882.5550) (JXG)

Type of 510(k) Submission: Special 510(k)

Basis for Submission: Materials Formulation Change

Predicate Device(s):		
	K944222	Codman® Hakim® Shunt System
	K974739	Codman® Hakim® Programmable Valve System
	K020667	Codman® Hakim® Shunt System
	K053350	Modification to Codman® Hakim® Shunt System
	K992173	Codman® SiphonGuard CSF Control Device

Device Description

The Codman HAKIM® Precision and Programmable Valve Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

Hydrocephalus is a condition caused by the excessive accumulation of CSF in the ventricles of the brain due to a disturbance of CSF secretion, flow, or absorption, which causes a rise in intracranial pressure (ICP). To relieve ICP, CSF can be diverted through a shunting device, such as the HAKIM® valve, to another body cavity where it is absorbed and subsequently excreted.

Both the HAKIM® Precision and Programmable valves are pressure regulating valves which maintain intraventricular pressure at a constant level. The HAKIM® Precision valves are fixed pressure valves and are available in 5 different opening pressure ranges. The HAKIM® Programmable valves not having fixed pressures, permit non-invasive adjustment of the valve opening pressure, in order for the surgeon to increase or decrease the valve's opening pressure, and can be adjusted to 18 different opening pressure settings.

The purpose of this Special 510(k) premarket notification is to request a material formulation change to the valve introducers that are used as accessories to the Hakim® Precision and Programmable Valve Systems.

Indications for Use

The HAKIM® Precision and Programmable Valve System is an implantable device that provides constant intraventricular pressure and drainage of CFS for the management of hydrocephalus. The material formulation change of the valve introducers does not affect the indications for use or the intended use of the HAKIM® Precision and Programmable Valve System.

Technological Characteristics

The material formulation change of the valve introducers does not affect the design, performance characteristics, or principles of operation of the HAKIM® Precision and Programmable Valve Systems. The technological characteristics of the modified valve introducers are identical to those of the predicate valve introducer devices. No changes are being made to the HAKIM® Precision or HAKIM® Programmable valves or any other accessory components provided with the valves.

Non-Clinical Performance Testing

Testing has been successfully completed and supports the safety and effectiveness of the modified valve introducers for their intended uses.

Clinical Performance Testing

The intention of this Special 510(k) is to seek clearance for a materials formulation change to the polyethylene material used on the valve introducers which are accessories to the HAKIM® Precision and Programmable Valve System. No clinical tests were required for this change.

Performance Data

Codman performed functional flex testing, pull testing, and biocompatibility testing in accordance with ISO-10993-1 and FDA Blue Book G95-1. The results of this testing

demonstrate that the materials formulation change to the Hakim® Precision and Programmable valve introducers has no affect on the performance of the HAKIM® Precision and HAKIM® Programmable Valve System.

Statement of Substantial Equivalence

The Codman® HAKIM® Precision and Programmable Valve Systems are substantially equivalent to the Codman® HAKIM® Precision and Programmable Valve Systems previously cleared by the FDA (K944222, K974739, K020667, K053350, and K992173) based on similarities in intended use, design, principles of operation, and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 3 2012

Codman & Shurtleff, Inc.
c/o Ms. Kathy A. Strange
Regulatory Specialist
325 Paramount Dr.
Raynham, MA 02767-0350

Re: K122118
Trade/Device Name: HAKIM® Programmable and Precision Valve Introducer
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: July 16, 2012
Received: July 17, 2012

Dear Ms. Strange:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah Falls

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122118

Device Name: Codman ® HAKIM ® Precision and Programmable Valve System

Indications for Use:

The HAKIM ® Precision Valve System is an implantable device that provides constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The HAKIM ® Programmable Valve System is an implantable device that provides constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Samuel Shimp

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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